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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,215	06/24/2003	Neema M. Kulkarni	PC 21501B	2258

28880 7590 12/09/2005

WARNER-LAMBERT COMPANY  
2800 PLYMOUTH RD  
ANN ARBOR, MI 48105

EXAMINER

COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



### **DETAILED ACTION**

Claims 1-14, 16 and 17 are pending and examined.

#### ***Claim Rejections - 35 USC § 112***

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants submit that claim 17 is fully supported in the specification as filed and does not introduce new matter. However, it is not seen that the specific limitations of the composition are recited in the specification, nor has Applicant pointed out where they may be found.

In view of the amendments to the claims the earlier rejection under 35 USC 112, paragraph one to enablement is withdrawn.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/59573 for the reasons given in the Office Actions of September 13, 2004, February 28, 2005 and June 17, 2005.

Applicants argue that WO 99/59573 does not suggest the limitations of polyhydric alcohol or pH in the composition or that said limitations would result in a stable liquid pharmaceutical composition. They further argue that Example 2 in WO 99/59573 shows that the addition of xylitol to gabapentin increases lactam formation and that it is the addition of glycine to gabapentin that decreases lactam formation, despite the presence of xylitol.

This is not persuasive, since the "comprising" language of the claims would allow for both xylitol and glycine as disclosed in WO 99/59573.

Applicants further argue that the Declaration under 37 CFR 1.132 submitted on May 27, 2005 provides stability data for a composition comprising 44 g glycerol and 30 g of xylitol per 100 ml of the composition. However, this is not stated in the Declaration. Furthermore, the Declaration does not compare stability data for the lower amount of polyhydric alcohol in instant composition with the amount of polyhydric alcohol in WO 99/59573.

#### **Action Is Final**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 571-273-8300.

Rebecca Cook



Primary Examiner  
Art Unit 1614

December 6, 2005